SPE RESPONSE FOR CERTIFICATE OF CORRECTION

Paper No.:20070122

DATE : January 22, 2007

TO SPE OF : ART UNIT 1625

SUBJECT : Request for Certificate of Correction on Patent No.: 6,962,924

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within **7** days to:
Certificates of Correction Branch - PK 3-910
Palm location **7590** - Tel. No. 305-8201

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Thank You For Your Assistance **Certificates of Correction Branch**

The request for issuing the above-identified correction(s) is hereby:
Note your decision on the appropriate box.

☒ **Approved** **All** changes apply.

☐ **Approved in Part** Specify below which changes **do not** apply.

☐ **Denied** State the reasons for denial below.

Comments:

SPE: **Art Unit** 1625

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : 6,962,924
DATED: : November 8, 2005
INVENTOR(S) : RAY ET AL.

It is certified that there is/are an error(s) in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, lines 4 and 5 should read:

-- This application claims the benefit of provisional application Ser. No. 60.401,153, filed on Aug. 5, 2002. --.

The allowed claims (8, 9, 11, 12, 16, 17, 19 and 20) have been renumbered as follows:

1. A Polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I_0"):

D	I/I_0
12.32	26
10.53	11
8.444	19
8.149	16
6.550	25
6.281	22
6.185	35
6.084	19
5.553	88
5.373	64
5.096	59
4.960	41
4.745	34
4.470	26

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PATENT NO. 6,962,924

FORM PTO-1050

OCT 1 9 2005

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4.403	30
4.365	46
4.159	84
4.124	73
4.061	35
3.750	79
3.716	100
3.659	27
3.589	14
3.398	11
3.362	16
3.277	10
3.090	23
3.051	11
3.003	15
2.784	10
2.507	12

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2. A Polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensity ("I/I_0"):

D	I/I_0
14.14	14
10.74	13
7.158	39
7.084	20
5.983	12
5.663	61
5.365	33
5.267	100
5.064	12
4.973	46
4.809	16
4.745	43
4.477	32
4.449	26
4.399	60
4.317	54
4.012	49

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3.772	26
3.745	61
3.722	97
3.590	88
3.561	59
3.385	24
2.986	17
2.949	11
2.836	20
2.778	10
2.616	10
2.481	12

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3. A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 1 according to Claim 1 and a pharmaceutically acceptable carrier.

4. A solid pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 according to Claim 2 and a pharmaceutically acceptable carrier.

5. A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 1 comprising:

(i) mixing an ethanolic solution of desloratadine and fumaric acid at a temperature of from about 15°C to about 25°C and stirring for 30-45 minutes at this temperature to form a solid; and

(ii) filtering the solid at this temperature to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 224°C ± 2°C.

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6. A process for preparing polymorph form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim1 comprising:

(a) dissolving desloratadine in anhydrous ethanol to form an ethanolic solution of desloratadine;

(b) dissolving fumaric acid in anhydrous ethanol to form an ethanolic solution of fumaric acid;

(c) mixing the ethanolic solution of desloratadine and the ethanolic solution of fumaric acid at a temperature of from about 15°C to about 25°C and stirring for 30-45 minutes at this temperature to form a solid; and

(d) filtering the solid at this temperature to form the polymorphic form 1 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 224°C ± 2°C.

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7. A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 2 comprising:

(i) mixing an ethanolic solution of desloratadine and fumaric acid at a temperature of from about 55°C to about 70°C and stirring for 30-45 minutes after mixing to form a solid; and

(ii) filtering the solid at this temperature to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C ± 2°C.

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8. A process for preparing polymorph form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate according to Claim 2 comprising:

(a) dissolving desloratadine in anhydrous ethanol to form an ethanolic solution of desloratadine;

(b) dissolving fumaric acid in anhydrous ethanol to form an ethanolic solution of fumaric acid;

(c) mixing the ethanolic solution of desloratadine and the ethanolic solution of fumaric acid at a temperature of from about 55°C to about 70°C and stirring for 30-45 minutes after mixing to form a solid; and

(d) filtering the solid at this temperature to form the polymorphic form 2 of 8-chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]-cyclohepta[1,2-b]pyridine hemifumarate which is characterized by a DSC of 232°C ± 2°C.

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